I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: December 9, 2008 Signature:

(Aaron S. Eckenthal)

Docket No.: TEVNHC 3.0-200

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Fiona Catherine Millar

Application No.: 08/999,752 Group Art Unit: 1615

Filed: June 4, 1997 Examiner: S. T. Tran

For: MEDICINAL AEROSOLS AND METHODS

OF DELIVERY THEREOF

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Applicant hereby advises the Patent Office that its corresponding EP0918507 B1, which is cited in the accompanying form PTO/SB/08a (10-08), has been the subject of an opposition proceeding in the European Patent Office. Thus, in accordance with the duty of disclosure as explained in the M.P.E.P. § 2001.06(c), Applicant submits not only the publications that were cited in the Opposition, but all substantive submissions lodged by both the two Opponents and the Proprietor during the course of the Opposition. Those documents, copies of which are enclosed, are listed below in the order in which they were filed with the EPO Opposition Division:

- 1. 12/14/2001 Merck Generics presenting observations with enclosed references.
- 2. 12/18/2002 3M Notice of Opposition to EPO.
- 3. 1/3/2003 Merck Generics Notice of Opposition to EPO.
- 8/22/2003 4. EPO observations on Notices of Oppositions filed by 3M and Generics.
- 3/24/2006 5. EPO Communication Summons to attend oral proceedings and instructions.

- 6. 7/4/2006 3M final submissions to EPO.
- 7. 8/4/2006 Patentees submission.
- 8. 8/10/2006 Generics written submissions.
- 9. 12/7/2006 Generics observation regarding patentees final submission of 8/4/2006.
- 10. 12/13/2006 Interlocutory decision in Opposition proceedings.
- 11. 12/13/2006 Minutes of the Oral Proceeding before the Opposition Division.
- 12. 12/19/2006 3M comments re amendments made by the patent proprietor during oral proceedings.
- 13. 2/16/2007 Generics Notice of Appeal.
- 14. 4/23/2007 Generics Statement of Grounds Appeal and accompanying documents filed in support of 2/16/2007 Notice of Appeal.
- 15. 4/24/2007 Replacement pages for previously submitted Generics Statement of Grounds Appeal for filing.
- 16. 11/20/2007 Patentees response to Grounds for Appeal.

The EPO Opposition Division ultimately determined that the claimed invention was patentable over the cited prior art, e.g., Schultz '747 and WO 95/17195. See, Interlocutory decision in Opposition Proceedings, at page 10. The Examiner may appreciate that the teachings in WO 95/17195 that were relied upon by the Opponents and the Opposition Division are similar in pertinent respects to those in Schultz '201.

Applicant respectfully requests that the information contained herein, the documents annexed hereto and the publications listed on the enclosed form, PTO/SB/08a (10-08) (which include publications in addition to those cited in the Opposition), be made of record and considered with respect to the captioned U.S. patent application. A copy of each

publication which is not a U.S. patent or patent application is Submission of the present Information Disclosure Statement should not be taken as an admission that the cited references are legally available prior art or that the same are pertinent or material.

In the event that any fee is due in connection with the present Information Disclosure Statement, the Commissioner is hereby authorized to charge the same to our Deposit Account No. 12-1095.

Dated: December 9, 2008

Respectfully submitted,

Ву_ Aaron S. Eckenthal Registration No.: 58,891 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, LLP 600 South Avenue West Westfield, New Jersey 07090 (908) 654-5000 Attorney for Applicant(s)

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